

Instructions for reagent target requests to the NCI Antibody Characterization Program

Concern about the lack of access to affordable, well-characterized and analytically validated renewable affinity reagents and supporting resources has been discussed among representatives of the cancer scientific community. In order to drive the development of a central community core that would help accelerate biomarker discovery and validation, cancer diagnostics development, and therapeutics monitoring, the National Cancer Institute (NCI) launched the Antibody Characterization Program. This program within the Clinical Proteomic Technologies for Cancer initiative (CPTC) provides reagents and other critical resources to support protein/peptide measurement and analysis efforts. For More information on this program and reagents currently available go to <http://proteomics.cancer.gov> and <http://antibodies.cancer.gov>. The CPTC Reagents Data Portal provides information and access for a large number of reagents in the CPTC initiative. Currently, monoclonal antibodies are being generated and characterized to proteins associated with human cancer. For each protein target, up to three monoclonal antibodies are generated and characterized using standardized assays that include (non inclusive list): isotype, SDS-PAGE, Western Blot, ELISA, Immunohistochemistry, Immuno Mass Spectroscopy and Surface Plasmon Resonance. Monoclonal antibodies and hybridoma cells are made available to the research community through the Developmental Studies Hybridoma Bank (DSHB) at the University of Iowa. All antibodies are expressed, purified, produced and characterized using standard operating procedures (SOPs) that are freely accessible to the public. Since not all antibodies selected will be applicable to specific utilities, reasonable efforts are made to select antibodies with as broad utility as possible.

Because this is a highly sought after resource, the NCI may not be able to satisfy all requests for antibody generation. Concomitantly, there are no guarantees that if the NCI attempts to make antibodies to the target protein request, that the antibodies will be successfully generated and/or useful in the application desired. The NCI reserves the right to deny requests that are deemed incompatible with the mission and goals of the NCI.

Requests will be reviewed and considered for merit based on their justification and contribution to existing NCI-funded projects. Priority will be given to projects applying the antibodies to proteomic research. Requests should be submitted electronically by completing the accompanying form.

For questions, please contact Dr. Tara Hiltke of the NCI:

E-mail: hiltket@mail.nih.gov
Phone: 301-451-8511
Address: 31 Center Drive
MS 2590
Bethesda, Maryland, 20892

Reagent target requests form
(All fields are required)

Investigator:
Institution:
Contact Person:
E-mail:
Telephone:
Fax:

Title of project for which materials are requested:

Investigators submitting must demonstrate that the target request is consistent with the mission of the NCI and that the target reagent will be further evaluated once created (i.e. NIH funded research or equivalent):

For each comment, please answer in 500 words or less

Antibody:

1. Describe why the antibody is required, the importance of the target and the research area to which it would benefit if the material was produced (do not include confidential/proprietary information).
2. Describe commercial antibody availability or lack thereof and any experience you have had with these antibodies.
3. Describe the intended application for the antibody (i.e. Western Blot, ELISA, IHC):

Antigen:

1. Describe the molecular weight of the antigen. A full length protein is desired, when possible, in order to create reagents which will bind native conformations. However, functional domain/protein fragments or peptides of interest will be considered.
2. Where was the antigen produced? What was the expression system (i.e. *E.coli*, mammalian, baculovirus, other)?
3. Provide the antigen amino acid sequence (do not provide confidential/proprietary information)?
4. How much protein/peptide will you provide for this project? Please note that a minimum of 3- 5 mg of protein/peptide is required for monoclonal antibody production, screening, counter screening (where applicable) and characterization (preferably endotoxin free) is required. If a different protein/peptide is needed for counter screening and/or characterization you will need to provide that as well (1 – 3 mg).
5. For monoclonal antibody generation, is the protein/peptide endotoxin free? How was this determined? If needed, NCI's Antibody Characterization Laboratory

will provide endotoxin removal to accepted targets, but more than 5 mg of protein may be needed since the removal process often leads to a loss of 10–50% of protein.

6. Does the protein/peptide contain any post-translational modifications (i.e. phosphorylation)? If yes, describe, if possible, how many modifications and the specific site(s)?
7. Is the protein/peptide soluble in a non-denaturing buffer (i.e. PBS)? Soluble proteins are desired, but insoluble proteins will be accepted.
8. Provide copies of gels or other characterization(s) that have been performed on the antigen to demonstrate purity, molecular weight, etc. Additionally, proteins received will be subjected to QC evaluation to assess purity, concentration and identification (SDS-PAGE, MALDI-TOF) and those which do not meet specifications will be rejected.
9. Provide any publications regarding the protein/peptide.

Please read and indicate (X) if you agree with the following statements:

- _____ If the protein/peptide target is selected for antibody generation, I understand the protein/peptide will undergo quality control (QC) to assess purity, concentration and identification (SDS-PAGE, MALDI-TOF, etc) before it is approved. Proteins/peptides that fail QC will be rejected.
- _____ I understand that there are no guarantees that if the NCI attempts to make antibodies to the target protein/peptide requested, that the antibodies will be successfully generated and/or useful in the application desired.
- _____ I understand that not all antibodies selected will be applicable to specific utilities. Reasonable efforts to select antibodies with as broad utility as possible will be made.
- _____ I understand that ALL antibodies, clones and hybridomas produced by this program will be made freely available for research use only to all researchers (non-profit, academic and commercial organizations) through the Developmental Studies Hybridoma Bank at the University of Iowa. Further, NCI will retain an archive of hybridomas/clones that successfully generated your antibody.
- _____ I and my organization confirm that we hold no background intellectual property on the target protein/peptide or materials supplied to the NCI for antibody production, screening and characterization.
- _____ One aliquot of each CPTC hybridoma/ clone generated to the protein/peptide will be returned to Provider. Provider is permitted to use these CPTC hybridoma/clones for research purposes consistent with the objectives of the CPTC program. Additionally, Provider is free to use these CPTC hybridoma/clones for commercial purposes such as production, screening, and sale.
- _____ Provider understands that NCI retains the independent right to negotiate agreements with commercial entities for the release of CPTC hybridoma/clones through the University of Iowa Hybridoma Bank. NCI has no plans to pursue this option except in exceptional circumstances where doing so is necessary to meet the objectives of CPTC for wide-spread distribution of Proteomic Resources.
- _____ I have signed and completed the attached Material Transfer Agreement.

Please return the completed form to Dr. Tara Hiltke:

E-mail: hiltket@mail.nih.gov
Phone: 301-451-8511
Address: 31 Center Drive
MS 2590
Bethesda, Maryland, 20892

MATERIAL TRANSFER AGREEMENT

Provider:

Recipient: The National Cancer Institute (“NCI”)

BACKGROUND

The Clinical Proteomic Technologies for Cancer (CPTC) initiative supported by the National Cancer Institute is working to optimize proteomic technologies and reagents for the entire cancer community, to accelerate the identification and validation of cancer biomarkers and potential drug targets that can dramatically improve the detection, treatment, and ultimately the prevention of cancer. In an effort to produce and distribute the highest quality and most useful resources to the scientific community, this MTA will be used to transfer materials to NCI for the purpose of producing highly-characterized proteomic resources for wide distribution to the research community.

1. Provider agrees to transfer to NCI the following Material:
2. This Material will be used by Recipient in connection with the following project ("Project") described with specificity as follows:

The Material will be used by NCI to produce proteomic resources which may include but not be limited to antibodies, hybridomas or arrays (“Proteomic Resources”) for widespread distribution to the research community which is consistent with the goals of the CPTC. An aliquot of hybridoma clones and/or DNA clones (“CPTC Clones”) made from the Material will be returned to Provider.

3. THIS MATERIAL MAY NOT BE USED IN HUMAN SUBJECTS. The Material will only be used by NCI for the Project described above, under suitable containment conditions and in compliance with all Federal rules and regulations applicable to the Project and the handling of the Material. All Parties acknowledge and agree that the Material provided to NCI may be shared with NCI’s consultants, contractors or agents to complete the Project. It is agreed among the Parties that Provider is providing no sensitive or proprietary information that may accompany the Material.
4. NCI agrees to retain control over this Material and further agrees not to transfer the Material to third parties without advance written approval of Provider except as so noted in Article 2. NCI will also retain for archive purposes only hybridomas it successfully generates against the Material.
5. All Parties acknowledge and agree that the Proteomic Resources produced using the Material as part of the Project will be widely distributed by the University of Iowa Hybridoma Bank for research purposes to nonprofit and academic and commercial organizations.
6. Permitted uses of CPTC Clones.
Under this Material Transfer Agreement, an aliquot of CPTC Clones will be returned to Provider. Provider is permitted to use the CPTC Clones for research purposes consistent with the objectives of the CPTC program. Additionally, Provider is free to use CPTC Clones for commercial purposes such as production, screening, and sale, subject to the following conditions:

- a) CPTC CLONES MAY NOT BE USED (BY PROVIDER OR ANY COMMERCIAL PARTNER/LICENSEE) IN HUMAN SUBJECTS RESEARCH.
- b) For any research use of CPTC Clones, or for any commercial use of CPTC Clones (either by Provider or by any commercial partner/licensee), Provider and/or commercial partner/licensee shall include the unique CPTC identifier(s) (i.e., CPTC-IL 18-2) in all downstream products/services or publications.
- c) For all commercial uses of CPTC Clones, and unless prohibited by law from doing so, Provider agrees to hold NCI harmless and to indemnify NCI for all liabilities, demands, damages, expenses and losses arising out of Provider's commercial use of the CPTC Clones. For all commercial uses of CPTC Clones by Provider's commercial partner/licensee, Provider shall include in that commercial arrangement language which specifies that commercial partner/licensee shall hold NCI harmless and to indemnify NCI for all liabilities, demands, expenses and losses arising out of commercial partner/licensee's use of the CPTC Clones.
- d) NCI is to be notified of any commercial activity by Provider or Provider's commercial partner/licensee so that the CPTC program can track how CPTC Clones are being used in commercial settings.

Notwithstanding the permitted commercial use of CPTC Clones by Provider under this Article 6, Provider understands that NCI retains the independent right to negotiate agreements with commercial entities for the release of CPTC Clones through the University of Iowa Hybridoma Bank. NCI has no plans to pursue this option except in exceptional circumstances where doing so is necessary to meet the objectives of CPTC for wide-spread distribution of Proteomic Resources and as so articulated in the background section of this Agreement.

7. THE MATERIAL IS BEING SUPPLIED TO NCI WITH NO WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. Provider makes no representations that the use of the Material will not infringe any patent or proprietary rights of third parties.

8. NCI MAKES NO REPRESENTATIONS OR WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE REGARDING THE RESULTING PROTEOMIC RESOURCES MADE USING THE MATERIAL AS PART OF THE PROJECT. Furthermore NCI makes no representations that the resulting Proteomic Resources made using the Material will not infringe any patent or proprietary rights of third parties.

9. Provider confirms that Provider's organization holds no background intellectual property rights either to the Materials or any use thereof.

10. Each Party shall retain title to any patent or other intellectual property rights in inventions made by its employees in the course of the Project. No indemnification for any loss, claim, damage or liability is intended or provided by any Party under this Agreement. The NCI, as an agency of the United States Government, assumes liability only to the extent provided under the federal Tort Claims Act, 28 U.S.C. 2671 et seq.

(Signatures Begin on the Following Page)

For the National Cancer Institute

Henry Rodriguez, PH.D.
Program Director, CPTC, NCI

Date

Tara Hiltke, PH.D.
Program Manager, CPTC, NCI

Date

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Jeffrey Thomas, PH.D., NCI
Authorized NCI Official

Date

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For PROVIDER

(Scientific or Business Contact)

Date

Authorized Official

Date

Address: